



15/1618

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Examiner: Zohreh A. FAY                      Art Unit: 1618  
Re:    Application of:                      Robert F. KAIKO et al.  
      Serial No.:                              09/992,936  
      Filed:                                    November 5, 2001  
      For:                                    **OPIOID AGONIST/OPIOID ANTAGONIST  
   ACETAMINOPHEN COMBINATION**  
      Docket No.:                            200.1102CP2

Mail Stop: Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

July 10, 2007

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. § 1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (1 page) for consideration by the Examiner in connection with the examination of the above-identified patent application.

In accordance with 37 C.F.R. 1.98(a)(2), a copy of each cited document is enclosed. If it is determined that a copy of any of the cited documents is missing, the Examiner is requested to contact the undersigned so that the missing copy may be forwarded.

It is respectfully requested that the documents listed on the accompanying Form PTO-1449 (1 page) be considered and made of record.

This Information Disclosure Statement is filed under 37 C.F.R. § 1.97(c) before the mailing of "any of a final office action under § 1.311, a notice of allowance under § 1.113, a

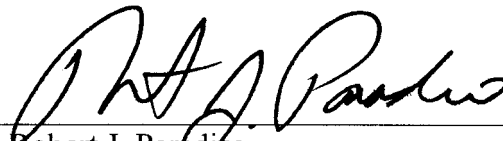
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notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application,” and is accompanied by a fee in the amount of \$180.00. If it is determined that any additional fee is due or overpayment made, the Examiner is authorized to charge said fee or credit said overpayment to Attorney Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: \_\_\_\_\_

  
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FORM PTO-1083  
Mail Stop: AMENDMENT  
COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, VA 22313-1450



Docket No.: 200.1102CP2  
Date: July 10, 2007

In re application of: Robert F. KAIKO and Robert D. COLUCCI  
Serial No.: 09/992,936  
Filed: November 5, 2001  
For: **OPIOID AGONIST/OPIOID ANTAGONIST/ACETAMINOPHEN COMBINATIONS**

S I r:

Transmitted herewith is an **Supplemental Information Disclosure Statement** (2 pages) in the above-identified application.

- ☐ Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.
- ☐ Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.
- ☒ No fee for additional claims is required.
- ☐ A filing fee for additional claims calculated as shown below, is required:

- ☐ Also transmitted herewith are:
  - ☐ Petition for three month extension under 37 C.F.R. 1.136(a)
  - ☒ Other: **PTO - 1449 (1 page) with copies of cited references.**

- ☒ Check(s) in the amount of **\$180.00** is/are attached to cover:
  - ☐ Filing fee for additional claims under 37 C.F.R. 1.16
  - ☐ Petition fee for three month extension under 37 C.F.R. 1.136(a)
  - ☒ Other: Information Disclosure Statement Fee

- ☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.

- ☐ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
- ☒ Any patent application processing fees under 37 C.F.R. 1.17.
- ☒ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

  
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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with sufficient postage to the United States Postal Service as "first class mail" in an envelope addressed to Mail Stop: Amendment "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on July 10, 2007.  
DAVIDSON, DAVIDSON & KAPPEL, LLC

BY:   
Oleg Ioselevich

FORM PTO-1449 (REV. 7-8)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1102CP2		SERIAL NO.: 09/992,936							
<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (Use several sheets if necessary)				APPLICANT(S): Kaiko et al.									
				FILING DATE: November 5, 2001		GROUP: 1618							
U.S. PATENT DOCUMENTS													
*EXAMINER INITIAL		DOCUMENT NUMBER						DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA												
	AB												
	AC												
	AD												
	AE												
	AF												
	AG												
	AH												
FOREIGN PATENT DOCUMENTS													
		DOCUMENT NUMBER						DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
												YES	NO
	AI												
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)													
	AJ	Philip D. Kanof et al., "Levels of Opioid Physical Dependence in Heroin Addicts," Drug and Alcohol Dependence, 27 (1991) 253-262.											
	AK	J.E. Peachey et al., "Assessment of Opioid Dependence with Naloxone," British Journal of Addiction (1988) 83(2), 193-201											
	AL	John G. Nutt et al., "Methadone-naloxone Mixtures for Use in Methadone Maintenance Programs," Clinical Pharmacology and Therapeutics, Vol. 15, Number 2, pp. 156-166, received for publication June 11, 1973											
	AM	Richard I. H. Wang et al., "Rating the Presence and Severity of Opiate Dependence," Clinical Pharmacology and Therapeutics, Volume 16, Number 4, pp. 653-657; received for publication January 21, 1974											
	AN	Richard B. Resnick et al., "Naloxone Precipitated Withdrawal: A Method For Rapid Induction Onto Naltrexone," Clinical Pharmacology and Therapeutics, Volume 21, Number 4, pp. 409-413; received for publication November 16, 1976											
	AO	Barbara A. Judson et al., "The Naloxone Test Opiate Dependence," Clin. Pharmacol. Ther., Vol. 27, Number 4, pp. 492-501, received for publication September 15, 1979											
	AP	Philip D. Kanof et al., "Clinical Characteristics of Naloxone-Precipitated Withdrawal in Human Opioid-Dependent Subjects," The Journal of Pharmacology and Experimental Therapeutics, Vol. 260, No. 1, pp. 355-363, 1992											
	AQ	Richard L. Wiesen et al., "The Safety and Value of Naloxone as a Therapeutic Aid," Drug and Alcohol Dependence, 2 (1977) pp. 123-130											
	AR												
	AS												
EXAMINER									DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													